

Application No.: 09/884,084

Amendment Dated: December 1, 2003

Reply to Office Action of: May 30, 2003

**REMARKS**

Applicants respectfully request reconsideration of the application, as amended, in view of the following remarks.

The present invention as set forth in **amended Claim 1** relates to a **porous hollow fiber membrane** obtained by a dry-wet spinning method or a wet spinning method from a spinning dope while using the following components:

a spinning dope containing a base polymer as a material for forming said porous hollow fiber membrane,

**an additive for facilitating a phase separation of said spinning dope,**

a solvent compatible with both, said base polymer and said additive, and

a mass of microparticles insoluble in said solvent, wherein said microparticles are uniformly dispersed in a liquid medium and have an average particle size within the range of 1 to 20  $\mu\text{m}$ , and

a coagulating liquid for forming the hollow fiber membrane,

to obtain a spun hollow fiber membrane; and

**extracting and removing said additive** and said microparticles by immersing said spun hollow fiber membrane into an extracting solution effective to dissolve said microparticles, but ineffective to dissolve said base polymer;

wherein said hollow fiber membrane has a permselectivity; wherein **a particle cutoff is within the range of 1 to 10  $\mu\text{m}$ ; and wherein a pure water permeate flow is equal to or higher than 30,000 L/m<sup>2</sup>/hr/100kPa.**

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**Amended Claim 6** relates to a method of making a porous hollow fiber membrane.

In contrast, Parham et al and Ruckenstein et al (US 5,993,661), neither disclose nor suggest the claimed membrane having a **particle cutoff of 1 to 10 $\mu$ m** or the claimed **water permeate flow**.

Parham et al (US 5,258,149) disclose a membrane having a pore diameter of **about 0.1 to about 0.7 microns** (Parham et al, col. 7, lines 49 and 50) which is much smaller than the claimed particle cutoff of **1 to 10 $\mu$ m**. There is no suggestion or motivation to go to a higher pore size as this would be detrimental to the filtration capability of the membrane for LDL cholesterol. **If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification** (*In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). Parham et al have chosen a specific pores size so that LDL cholesterol can be filtered from whole blood. Parham et al state at col. 7, lines 41-50 as follows:

“ The dimensional and porosity characteristics of the membranes of this invention are such that **LDL-C can pass through the fiber wall but most blood cells do not**. Hemolysis occurs if numerous blood cells pass through the fibers, **which is highly undesirable**.....Generally speaking, membranes can be prepared which possess a pore diameter of between about 0.1 microns to about 0.7 microns, preferably between 0.4 and 0.65 microns.”

Thus, Parham et al clearly teach away from larger pore sizes as they would lead to undesirable hemolysis. If the pore size of Parham et al were increased, the membrane would be completely useless. Since an increase in pore size of Parham et al would render the

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membrane completely useless, there cannot be any suggestion or motivation to increase the pore size.

In addition, since the membrane of Parham et al does not have the claimed pore size it **cannot have the claimed water permeate flow**. This is further shown by Comparison Example 2 at page 33 of the specification. Here a membrane with a particle cutoff of **0.85 micron** was prepared. The corresponding pure water permeate flow is only **22,000 L/m<sup>2</sup>/hr/100kPa**, which is much lower than the **claimed** pure water permeate flow of **30,000 L/m<sup>2</sup>/hr/100kPa**. A smaller pore size such as disclosed in Parham et al would yield an even smaller pure water permeate flow.

Furthermore, one feature of the present invention is to use **an additive** such as ethylene glycol mentioned in the specification on page 29, line 1 (Example 1). The pore size resulting in the particle cutoff claimed in Claims 1 and 6 can be attained by using the claimed additive for facilitating a phase separation of the spinning dope. As mentioned in the specification at page 11, lines 22-24, addition of one or more additives is effective to enhance a phase separation of the spinning dope, which eventually results information of the hollow fiber membrane having a relatively large pore size. Furthermore, as mentioned on page 12, lines 1 to 7, an appropriate selection of the additive amount and mixture of the microparticles contributes further in providing large size pores. Moreover, Applicants attach herewith a **Rule 132 Declaration** showing the influence of the additive on the pore size.

The results obtained **with additive (Examples 1, 3 and 5)** or **without additives (Examples 2, 4 and 6)** are summarized in the Tables below:

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	<b>Example 1</b> polysulfone	20 wt%	<b>Example 2</b> polysulfone	20 wt%
spinning dope				
	ethylene glycol	6 wt%	ethylene glycol	—
	silicone oxide (4.5 im)	18 wt%	silicone oxide (4.5 im)	18 wt%
	N,N-dimethyl acetoamide	54 wt%	N,N-dimethyl acetoamide	60 wt%
	<b>135000 L/m<sup>2</sup>/hr/100KPa</b>		<b>985 L/m<sup>2</sup>/hr/100KPa</b>	
pure water permeate flow particle cutoff	<b>2.4 μm</b>		<b>0.9 μm</b>	
	<b>Example 3</b> polysulfone	20 wt%	<b>Example 4</b> polysulfone	20 wt%
spinning dope				
	ethylene glycol	6 wt%	ethylene glycol	—
	silicone oxide (11 im)	20 wt%	silicone oxide (11 im)	20 wt%
	silicone oxide (4.5 im)	2 wt%	silicone oxide (4.5 im)	2 wt%
	N,N-dimethyl acetoamide	52 wt%	N,N-dimethyl acetoamide	58 wt%
	<b>520000 L/m<sup>2</sup>/hr/100KPa</b>		<b>1746 L/m<sup>2</sup>/hr/100KPa</b>	
pure water permeate flow particle cutoff	<b>5.0 μm</b>		<b>2.1 μm</b>	
	<b>Example 5</b> polysulfone	20 wt%	<b>Example 6</b> polysulfone	20 wt%
spinning dope				
	ethylene glycol	4 wt%	ethylene glycol	—
	silicone oxide (1.5 im)	14 wt%	silicone oxide (1.5 im)	14 wt%
	N,N-dimethyl acetoamide	62 wt%	N,N-dimethyl acetoamide	66 wt%
	<b>39000 L/m<sup>2</sup>/hr/100KPa</b>		<b>5567 L/m<sup>2</sup>/hr/100KPa</b>	
pure water permeate flow particle cutoff	<b>1.2 μm</b>		<b>0.9 μm</b>	

From the results shown in the above Tables, it is clear that the additive in the present invention contributes greatly in obtaining the claimed pure water permeate flow and the claimed particle cutoff. Thus, superior results are obtained using the additive according to the present invention. Applicants wish to draw the Examiner's special attention to the electron

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**microphotographs attached to the Rule 132 Declaration** which further illustrate the superior properties of the membranes according to the present invention.

In order to cure the defects of Parham et al, the Examiner cites Ruckenstein et al (US 5,993,661). However, Ruckenstein et al do not cure these defects because they also fail to disclose or suggest the claimed membrane having a particle cutoff of 1 to 10 $\mu$ m or the claimed water permeate flow. Ruckenstein et al disclose the use of silica particles of large size, for example, 15 to 40 microns. This particle size is much larger than the claimed particle size. In addition, if the pore size of Parham et al (0.1 microns to about 0.7microns) was modified to a pore size of 15-40 microns using the particle size of Ruckenstein et al (Ruckenstein et al, col. 4, line 48), **Parham et al's membrane would be rendered useless as it would pass not only the LDL-C but also most blood cells.** Thus, there is no suggestion or motivation to modify the pore size of Parham et al to that of Ruckenstein et al.

In addition, Ruckenstein et al fail to disclose or suggest the superior properties obtained with the claimed additive.

Even further, Ruckenstein et al uses a **flat membrane** and not a porous hollow membrane as claimed. Membrane forming conditions for the hollow membrane are severer than those for the flat membrane of Ruckenstein et al and accordingly, in the hollow membrane pores formed by the particles tend to shrink resulting in a much smaller size of the pores.

Stengaard also does not cure the defects of Parham et al and Ruckenstein et al because it also fails to disclose or suggest the claimed membrane having a particle cutoff of 1 to 10 $\mu$ m

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or the claimed water permeate flow. As discussed above, there is no motivation to modify the pore size of Parham et al. In addition, Stengaard fails to disclose or suggest the superior properties obtained with the claimed additive.

Therefore, the rejection of Claims 1-4, 6-8, and 29-30 under 35 U.S.C. §103(a) as being unpatentable over Parham et al (US 5,258,149) or Parham et al (US 5,258,149) in view of Ruckenstein et al (US 5,993,661) and the rejection of Claims 5 and 9 under 35 U.S.C. §103(a) as being unpatentable over Parham et al (US 5,258,149) or Parham et al (US 5,258,149) in view of Ruckenstein et al (US 5,993,661), and further in view of Stengard (US 5,019,261) are believed to be unsustainable as the present invention is neither anticipated nor obvious and withdrawal of these rejections is respectfully requested.

Applicants also appreciate the indication of a rejoinder of Claims 10-28 after allowability of the above Claims has been determined (see Office Action of November 22, 2002).

In addition, Applicants appreciate that the Examiner has sent signed copies of all IDS filed in this application by facsimile on December 20, 2002. However, with respect to the **Form PTO-1449 of March 6, 2002**, it appears on the facsimile copy that the second reference (**U.S. 5,976,433**) has not been initialed. Thus, **Applicants respectfully request that the Examiner sends another copy of Form PTO-1449 of March 6, 2002**, in which the second reference has been initialed as well. For the Examiner's convenience a copy of Form PTO 1449 as filed on **March 6, 2002**, is attached herewith.

Applicants respectfully request that the Examiner acknowledge that the references

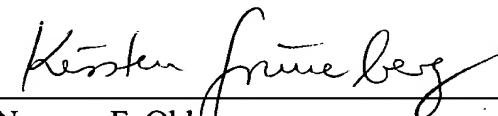
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cited in the **Information Disclosure Statement**, filed in the above-identified application on **October 21, 2003**, have been considered. For the Examiner's convenience a copy of Form PTO 1449 as filed on **October 21, 2003**, is attached herewith.

This application presents allowable subject matter, and the Examiner is kindly requested to pass it to issue. Should the Examiner have any questions regarding the claims or otherwise wish to discuss this case, he is kindly invited to contact Applicants' below-signed representative, who would be happy to provide any assistance deemed necessary in speeding this application to allowance.

Respectfully submitted,

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